



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/660,461

09/10/2003

Christopher J. Calhoun

MA9758P

4950

7590 10/23/2007
Stout, Uxa, Buyan & Mullins, LLP
Suite 300
4 Venture
Irvine, CA 92618

EXAMINER

HAGOPIAN, CASEY SHEA

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

10/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/660,461

Applicant(s)

CALHOUN, CHRISTOPHER J.

Examiner

Casey Hagopian

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-6, 8-10 and 22 is/are rejected.
- 7) ☒ Claim(s) 2, 3, 7, 11, 23 and 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Art Unit: 1615

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 7/24/2007.

Claims 1-11 and 22-24 are currently pending.

MAINTAINED REJECTIONS

The following rejection is maintained from the previous Office Action dated 5/11/2007. Applicant's amendment to claim 1 has broadened the scope of said claim such that the art applied previously to claim 21 is now relevant to at least claim 1. Thus, the rejection is necessitated by applicant's amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4-6, 8-10 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totakura et al. (USPN 5,795,584). Totakura teaches a surgical adhesion barrier and methods thereof comprising bioabsorbable materials made of copolymers of carbonates and at least one other bioabsorbable polymer forming material, preferably a lactide copolymer (abstract; column 2, lines 26-38; column 3, lines 36-51). The adhesion barrier is in the form of a substantially uniform, non-porous film and capable of comprising a medicinal agent including peptides (column 5, lines 25-52; column 10, lines 25-41). The barrier is also resilient, flexible and conformable allowing a surgeon to shape the device to fit the area of injury (column 4, lines 58-63; column 10, lines 54-60). In fact, Totakura teaches that the invention can be used for open general surgery and prevents formation of surgical adhesions at a surgical wound when the barrier is interposed between the surgical wound and the surrounding tissue (column 3, lines 7-9 and 19-22). Totakura further teaches the invention is generally used in the form of a sheet (i.e. substantially smooth) and may be shaped to conform to particular injury site and/or may be wrapped around an organ (column 10, lines 53-60). The device may also be affixed to the wound site (col. 10, lines 65-67). Totakura also teaches that the adhesion barrier has a thickness in the range of about 0.1-100 mils (column 5, lines 37-42), which translates to a thickness range of 2.54-2,540 microns because 1 mil is equivalent to one-thousandth of an inch or 25.4 microns (<http://rel.intersil.com/docs/lexicon/M.html>, page 3 of 6).

Totakura is silent to the particular placement of the membrane being at the opening of pericardial tissue; however, Totakura teaches the generic placement of the

Art Unit: 1615

membrane between the site of injury and the surrounding tissue as well as the use of the membrane for open general surgery and prevention of surgical adhesions. Totakura also cites the article, "Prevention of postoperative pericardial adhesions by closure of the pericardium with absorbable polymer patches" (Malm et al.) under the *Other Publications* section (page 2) of the patent, which suggests that pericardial adhesions as well as pericardial patches are well known in the art. Thus, one of ordinary skill in the art would be motivated to apply Totakura's generic teaching of placing the membrane between the site of injury and the surrounding tissue for the specific purpose of treating pericardial adhesions. A practitioner would reasonably expect the placement of a surgical adhesion barrier on the pericardium would effectively treat pericardial adhesions. Thus in Totakura, it would have been obvious to one skilled in the art at the time the invention was made to include the particular placement of the membrane being at the opening of pericardial tissue.

Totakura is silent to the particular resorption period of approximately 18 to 24 months; however, Totakura provides motivation to alter the rate of bioabsorption in the following disclosure,

"...the rate of bioabsorption of each bioabsorbable layer can be varied by changing the chemical make up and/or thickness of each successive layer. Various bioabsorbable polymers, copolymers and/or blends thereof are known to have different rates of absorption. For example, bioabsorbable polymers having a high degree of crystallinity are absorbed less rapidly than bioabsorbable polymers having relatively higher amounts of amorphous regions. Thus, rates of bioabsorption can be engineered to fit particular needs" (column 9, lines 45-54).

One of ordinary skill in the art would have been motivated to achieve a resorption period of approximately 18 to 24 months by varying the chemical make up or thickness of the barrier in order to, for example, continue to elute a medicinal agent directly at the site of

Art Unit: 1615

implantation depending on the needed treatment regime. A practitioner would have reasonable expectation that the adhesion barrier taught by Totakura would continue to release a therapeutic agent at the site of implantation for various durations including approximately 18 to 24 months. Thus in Totakura, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to alter the resorption rate of the adhesion barrier to approximately 18 to 24 months.

Totakura is silent to sterile packaging; however, it is the position of the examiner that it is well known in the art that the surgical materials are sterilized prior to packaging or while packaged by way of, for example, irradiation. One would be motivated to provide the membrane in a sterile package for two main reasons: 1) ease of storage and transportation and 2) reduce the chance of infection in a patient. Thus, in Totakura it would have been obvious for one skilled in the art to include sterile packaging.

Response to Arguments

Applicant's amendments render all previous rejections under 35 USC 112 moot.

Thus, the rejections under 35 USC 112 have been withdrawn.

The cancellation of claim 21 renders the rejection under 35 USC 103 moot.

Thus, the rejection of claim 21 under 35 USC 103 has been withdrawn.

Conclusion

Claims 1, 4-6, 8-10 and 22 have been rejected and claims 2, 3, 7, 11, 23 and 24 are objected to as being dependent on a rejected base claim; no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm.

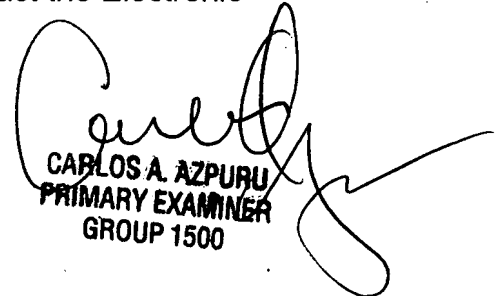
Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey Hagopian/

Casey Hagopian
Examiner
Art Unit 1615


CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500